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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products
Liability Litigation

No. MD-15-02641-PHX-DGC

**PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF
CLEMENT J. GRASSI, M.D.**

Pursuant to Federal Rule of Evidence 702, Plaintiffs move this Court for an order excluding the opinions and testimony of Defendants' expert witness Clement J. Grassi, M.D. because his methods, opinions, and testimony do not comport with the legal requirements of an expert witness. Plaintiffs' motion is supported by the Memorandum of Law set out below and exhibits attached thereto.

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE
TESTIMONY OF CLEMENT J. GRASSI, M.D.**

Plaintiffs submit this "Memorandum in Support of Plaintiffs' Motion to Exclude Testimony of Clement J. Grassi, M.D." For the reasons set forth below an Order should be entered excluding the following areas of Dr. Grassi's testimony:

**I.
SUMMARY OF PLAINTIFFS' ARGUMENT**

Clement J. Grassi, M.D. is a board certified Interventional Radiologist. Dr. Grassi is not qualified to give opinions which are not derived from his field of expertise.

1 Plaintiffs ask this Court to enter an order precluding testimony from the areas outlined
2 below.

3 **II.** 4 **EVIDENCE**

5 In support of this motion, Plaintiffs rely on the following documents:

- 6 A. The deposition transcript of Clement J. Grassi, M.D. (June 15, 2017)
(hereinafter “Deposition”) (Exhibit “A”); and
- 7 B. Dr. Grassi’s curriculum vitae, (Exhibit “B”).

8 **III.** 9 **ARGUMENT AND AUTHORITIES**

10 **A. UNDER THE GOVERNING *DAUBERT* STANDARD, DR. GRASSI’S 11 CHALLENGED OPINIONS SHOULD BE EXCLUDED.**

12 “The fields of knowledge which may be drawn upon are not limited merely to the
13 ‘scientific’ and ‘technical’ but extend to all ‘specialized’ knowledge.” *Butler v. Home*
14 *Depot*, 984 F. Supp. 1257, 1261 (N.D. Cal. July 31, 1997). Pursuant to Federal Rule of
15 Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 113 S. Ct. 2786,
16 125 L.Ed.2d 469 (1993), expert testimony must be relevant, and must assist the trier of
17 fact. “The question of admissibility only arises if it is first established that the individuals
18 whose testimony is being proffered are experts in a particular scientific field.... something
19 doesn’t become “scientific knowledge” just because it’s uttered by a scientist” *Daubert v.*
20 *Merrell Dow Pharmaceuticals*, 43 F.3d 1311 (9th Cir. Cal. Jan. 4, 1995). In analyzing the
21 reliability of proposed expert testimony, the role of the court is to determine whether the
22 expert is qualified in the relevant field and to examine the methodology the expert has
23 used in reaching his conclusions. An expert may be qualified by knowledge, skill,
24 experience, training, or education. Fed. R. Evid. 702; *Smith v. Ford Motor Co.*, 215 F.3d
25 713, 716 (7th Cir. Ind. June 2, 2000).

26 As established by the Supreme Court in *Daubert, supra*, a trial court acts as a
27 “gatekeeper” to the admission of expert scientific testimony under Rule 702. The court
28 must conduct a preliminary assessment to “ensure that any and all scientific testimony or
evidence admitted is not only relevant, but reliable.” *Id.* at 589, 113 S.Ct. 2786. This two-

1 step assessment requires consideration of whether (1) the reasoning or methodology
 2 underlying the testimony is scientifically valid (the “reliability” prong); and (2) whether
 3 that reasoning or methodology properly can be applied to the facts in issue (the
 4 “relevancy” prong). *Id.* at 592-93, 113 S.Ct. 2786; *Kennedy v. Collagen Corp.*, 161 F.3d
 5 1226, 1228 (9th Cir.1998). The expert’s testimony must be based on knowledge, not mere
 6 subjective belief or unsupported speculation. *Wright v. United States*, 2008 U.S. Dist.
 7 LEXIS 24016, 20 (D. Ariz. Mar. 25, 2008).

8 Thus, an expert’s work is admissible “only to the extent it is reasoned, uses the
 9 methods of the discipline, and is founded on data. Talking off the cuff—deploying neither
 10 data nor analysis—is not an acceptable methodology.” *Lang v. Kohl’s Food Stores, Inc.*,
 11 217 F.3d 919, 924 (7th Cir. 2000). “The proponent of the expert testimony bears the
 12 burden of establishing the testimony’s admissibility by a preponderance of the evidence.”
 13 *Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 598 (9th Cir. 1996); *Butler v.*
 14 *Home Depot*, 984 F. Supp. 1257, 1260 (N.D. Cal. July 31, 1997). “The suggested
 15 scientific testimony must ‘fit’ the issue to which the expert is testifying. *Chapman v.*
 16 *Maytag Corp.*, 297 F.3d 682, 687 (7th Cir.2002). “A district judge asked to admit
 17 scientific evidence must determine whether the evidence is genuinely scientific, as distinct
 18 from being unscientific speculation offered by a genuine scientist.” *Rosen v. Ciba-Geigy*
 19 *Corp.*, 78 F.3d 316, 318 (7th Cir. Ill. Mar. 11, 1996).

20 **1. Dr. Grassi is not Qualified to Opine on Standards, Practices, Procedures,**
 21 **Testing, Processes, and/or the Responsibilities of the Food and Drug**
Administration.

22 Dr. Grassi has no education, training or experience in the area of FDA standards,
 23 practices, procedures, testing, processes, and/or the responsibilities of the Food and Drug
 24 Administration. Dr. Grassi’s curriculum vitae, [Exhibit B], is devoid of any training,
 25 education or experience to qualify his testimony relating to the FDA as reliable.

26 At his deposition, he was asked “What evidence are you aware of in the medical
 27 literature that supports that mechanism as explaining fractures” [Grassi Depo. 96:19-21].
 28 As part of his answer Dr. Grassi stated “I’m aware of the testing that goes on by different

1 manufactures on the benchtop and through repetitive stress testing. I know from personal
2 experience when I participated in the Simon Nitinol FDA pre-approval testing what was
3 done in terms of testing with that filter devise.” [Grassi Depo. 96-97:24-6].

4 Dr. Grassi testified that he is aware of the processes and standards that Bard is
5 required to undergo as part of its FDA pre-acceptance testing under a 510(k) application.
6 [Grassi Depo. 156:19-23]. Dr. Grassi qualifies this same statement with a mere
7 supposition that “he believes he is correct on this, benchtop testing and stress testing of
8 the device over many hundreds of thousands of cycles. However, I have not been provided
9 the specific documents on that topic.” [Grassi Depo. 157:1-4]. In this case, Bard has done
10 its own analysis, encompassing engineering, failure rates and internal bench testing.
11 Dr. Grassi readily admitted he has not been provided or reviewed this information. Bard
12 made a choice not to show him internal documents, or Dr. Grassi has simply not seen fit
13 to review this information. Dr. Grassi is unqualified to provide reliable testimony as these
14 areas are outside his field of expertise and his opinions are based upon no internal Bard
15 documents. This series of facts results in unqualified testimony and unreliable
16 methodology.

17 Plaintiffs do not dispute Dr. Grassi’s qualifications as an interventional radiologist;
18 however, Dr. Grassi’s opinions that are not derived from his field of expertise are without
19 foundation, irrelevant, unreliable and only serve to mislead the jury into assuming
20 Dr. Grassi is qualified to offer testimony reserved for FDA experts. Dr. Grassi should be
21 prohibited from offering any testimony beyond his qualifications. Specifically, he should
22 be excluded from offering opinions related to the FDA standards, practices, procedures,
23 testing, processes, and/or the responsibilities of the Food and Drug Administration and its
24 role in regulating and assuring the safety of IVC filters.

25 The above testimony supports Plaintiffs’ request for an Order excluding such
26 opinions from Dr. Grassi. Plaintiffs restate that Dr. Grassi’s curriculum vitae, [Exhibit B],
27 is absent any training, education or experience to qualify his testimony relating to the
28 FDA as reliable. Moreover, his methodology (or lack of) is unreliable, inaccurate and

1 unable to withstand reproduction. Dr. Grassi's general experience as a practitioner does
 2 not qualify him to provide testimony on FDA standards, practices, procedures, testing,
 3 processes, and/or the responsibilities of the Food and Drug Administration. Allowing his
 4 testimony would be to improperly put the label of an expert behind opinions which are
 5 "off the cuff," speculative, do not fit the issue for which Dr. Grassi is testifying and
 6 amount to nothing more than unqualified statements which if admitted would be
 7 prejudicial, misinform, and confuse a jury.

8 **IV.**
 9 **CONCLUSION**

10 Plaintiffs respectfully request that the Court exclude the expert testimony of
 11 Clement J. Grassi, M.D. in the areas identified above.

12 RESPECTFULLY SUBMITTED this 24th day of August, 2017.

13 GALLAGHER & KENNEDY, P.A.

14 By: /s/ Mark S. O'Connor

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of August, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti